PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 12 April 1999 (12.04.99)	
International application No. PCT/CA98/00697	**Applicant's or agent's file reference** 1038-827 MIS/bh
International filing date (day/month/year) 16 July 1998 (16.07.98)	**Priority date** (day/month/year) 18 July 1997 (18.07.97)
Applicant LI, Xiaomao et al	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   16 February 1999 (16.02.99)

   [ ] in a notice effecting later election filed with the International Bureau on:

   _____

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer S. Mafla
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

2563802

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
1038-827 MIS/bh		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CA 98/ 00697	16/07/1998	18/07/1997
Applicant		
CONNAUGHT LABORATORIES LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [X] **Certain claims were found unsearchable** (see Box I).

2. [ ] **Unity of Invention is lacking** (see Box II).

3. [X] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [X] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] Transcribed by this Authority

4. With regard to the **title,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:
   Figure No. 8
   - [ ] as suggested by the applicant.
   - [ ] because the applicant failed to suggest a figure.
   - [X] because this figure better characterizes the invention.
   - [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 98/00697

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Remark: Although claims 15-39 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INT ATIONAL SEARCH REPORT

rnational Application No
PCT/CA 98/00697

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12N15/45 A61K48/00 G01N33/53 C07K16/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	STOTT E J ET AL: "Human respiratory syncytial virus glycoprotein G expressed from a recombinant vaccinia virus vector protects mice against live-virus challenge." JOURNAL OF VIROLOGY, (1986 NOV) 60 (2) 607-13. JOURNAL CODE: KCV. ISSN: 0022-538X., XP002080963 United States see page 607 see abstract see page 608 'Results', first paragraph see page 609; figure 1 --- -/--	30-35

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 October 1998	30/10/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sitch, W

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Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	HSU K H ET AL: "Immunogenicity of recombinant adenovirus- respiratory syncytial virus vaccines with adenovirus types 4, 5, and 7 vectors in dogs and a chimpanzee." JOURNAL OF INFECTIOUS DISEASES, (1992 OCT) 166 (4) 769-75. JOURNAL CODE: IH3. ISSN: 0022-1899., XP002080964 United States see page 769 see abstract ---	30-35
X	STOTT E J ET AL: "Immune and histopathological responses in animals vaccinated with recombinant vaccinia viruses that express individual genes of human respiratory syncytial virus." JOURNAL OF VIROLOGY, (1987 DEC) 61 (12) 3855-61. JOURNAL CODE: KCV. ISSN: 0022-538X., XP002080965 United States see page 3855 see abstract see page 3856, 'Materials and Methods', first and second paragraphs ---	30-35
X	ELANGO N ET AL: "Resistance to human respiratory syncytial virus (RSV) infection induced by immunization of cotton rats with a recombinant vaccinia virus expressing the RSV G glycoprotein." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA, (1986 MAR) 83 (6) 1906-10. JOURNAL CODE: PV3. ISSN: 0027-8424., XP002080966 United States see page 1906 see abstract see page 1907; figure 1 ---	30-35
A	ROBERTS S R ET AL: "The membrane-associated and secreted forms of the respiratory syncytial virus attachment glycoprotein G are synthesized from alternative initiation codons." JOURNAL OF VIROLOGY, (1994 JUL) 68 (7) 4538-46. JOURNAL CODE: KCV. ISSN: 0022-538X., XP002080967 United States see page 4538 see abstract see page 4541; figure 1 --- -/--	5,6,8,9, 19,20, 22,23, 28,32,33

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	NGUYEN T N ET AL: "Hydrophobicity engineering to facilitate surface display of heterologous gene products on Staphylococcus xylosus." JOURNAL OF BIOTECHNOLOGY, (1995 OCT 16) 42 (3) 207-19. JOURNAL CODE: AL6. ISSN: 0168-1656., XP000561819 Netherlands see page 207 see abstract ---	5,6,8,9, 19,20, 22,23, 28,32,33
A	WATHEN M W ET AL: "Characterization of a novel human respiratory syncytial virus chimeric FG glycoprotein expressed using a baculovirus vector." JOURNAL OF GENERAL VIROLOGY, (1989 OCT) 70 (PT 10) 2625-35. JOURNAL CODE: I9B. ISSN: 0022-1317., XP002080968 ENGLAND: United Kingdom see page 2625 see abstract ---	5,6,8,9, 19,20, 22,23, 28,32,33
A	US 5 620 896 A (HERRMANN JOHN E ET AL) 15 April 1997 see column 2, line 62 - column 5, line 31; figures 1A,1B,3,4A,4B ---	1-29, 36-48
P,X	SCHRIJVER R S ET AL: "Comparison of DNA application methods to reduce BRSV shedding in cattle" VACCINE, vol. 16, no. 2-3, 2 January 1998, page 130-134 XP004098613 see the whole document ---	1-48
P,X	JOHNSON T R ET AL: "Priming with secreted glycoprotein G of respiratory syncytial virus (RSV) augments interleukin-5 production and tissue eosinophilia after RSV challenge." JOURNAL OF VIROLOGY, (1998 APR) 72 (4) 2871-80. JOURNAL CODE: KCV. ISSN: 0022-538X., XP002080969 United States see page 2871 see abstract -----	30-35

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 98/00697

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5620896 A	15-04-1997	US 5643578 A	01-07-1997
		AU 3150295 A	07-11-1996
		EP 0821583 A	04-02-1998
		WO 9632932 A	24-10-1996
		CA 2181832 A	03-08-1995
		EP 0740704 A	06-11-1996
		JP 9508622 T	02-09-1997
		WO 9520660 A	03-08-1995
		CA 2132836 A	30-09-1993
		EP 0633937 A	18-01-1995
		JP 7507203 T	10-08-1995
		WO 9319183 A	30-09-1993

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
1038-827 MIS/bh		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA98/00697	16/07/1998	18/07/1997
International Patent Classification (IPC) or national classification and IPC C12N15/45		
Applicant CONNAUGHT LABORATORIES LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16/02/1999	12.10.99
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Roscoe, R Telephone No. +49 89 2399 2554

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA98/00697

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-33	as originally filed				

Claims, No.:

1-48	as received on	02/09/1999	with letter of	02/09/1999	

Drawings, sheets:

1/19-19/19	as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5-29, 32-48
	No:	Claims	1-4, 30, 31
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-48
Industrial applicability (IA)	Yes:	Claims	1-14, 40-42, 45, 46, 48
	No:	Claims	15-39, 43, 44, 47

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1. Citations

The documents mentioned in the present written opinion / International Preliminary Examination Report are numbered as in the search report, i.e. D1 corresponds to the first document of the search report etc.

The priority document pertaining to the present application was not available at the time of establishing this first written opinion. Hence, the current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this assumption is incorrect, documents D9 and D10 cited in the search report could become relevant to the assessment of whether the present application satisfies the criteria set forth in Article 33(1) PCT.

2. Reasoned statement on Novelty, Inventive Step and Industrial Applicability (Section V)

2.1 Novelty (Art.33(2) PCT)

Applicant now claims that the vector cannot replicate at the site it is introduced into a host. Such a definition cannot be used in a claim for a vector or composition comprising such. This sort of definition is only acceptable where a vector-host combination is specified and the ability to replicate is defined in this context. The vectors used in documents D1-D4 and D7 could all be considered as unable to replicate in certain hosts or in certain tissues within a host.

The replication status of the recombinant Vaccinia viruses of D1, D3 and D4 is considered as follows:

The virus of D1 is administered by scarification of the hind to rabbits and intraperitoneally or intranasally to mice. The recombinant viruses appear to retain the ability to replicate in normal host cells (discussion, lines 5-8).

In D3, mice were vaccinated intranasally, intraperitoneally or by scarification of the tail, or cotton rats were vaccinated intradermally. Different vectors were used compared to those in D1 and thus conclusions on the ability to replicate can not be drawn from one document to the other. In the discussion (l.18) it is suggested that limited replication may or may not occur in the mouse following intranasal vaccination. Further, the statement that "a small proportion may have initiated infection" following scarification suggests that replication is considered to be occurring at this site.

D4 relates to intra-dermal and intra-nasal challenge of cotton rats. Again it is suggested that the virus replicates in the host (see p.1909, col.2, 2nd full para:"The wide host range..."). However it is not clear that this occurs following intradermal innoculation. This will have to be addressed by the applicant.

Claims 1-47 are all limited to the use of a "vector that will not replicate when introduced into the host to be protected". D1, D3 and D4 are not cited as novelty-destroying against these claims under the provision that a suitable terminology is found (which must of course have a basis in the application documents as originally filed).

With regard to the Adenovirus vectors of D2, Ad4 and Ad7 vectors expressing RSV G protein were used to immunize dogs by the intratracheal route. UV-inactivated and thus non-replicating viruses were also used. Ad4 does not appear to replicate significantly in the dog lung anyway (see p.769, last para.). The suggestion that D2 cannot be considered to anticipate the present claims as these require that protective antibodies are formed is considered untenable. Protective antibodies will be formed - they may not be formed at the same level (this also would depend on the amounts inoculated anyway). Hence, document D2 anticipates claims 1-4, 30 and 31.

2.2 Inventive Step (Art.33(3) PCT)

As can be seen from section 2.1, the concept of using an RSV G protein-expressing vector to immunize against RSV respiratory tract infections is well known in the prior art. Both replicative and non-replicative (at the administration

site) vectors have been used. The use of well known promoters / enhancers or specific sequences cannot be considered to confer inventivity to a process of vaccination against RSV using G protein-expressing vectors unless linked to some surprising effect. Given that it was known that G protein could elicit a significant and protective immune response to RSV, that the type of antibodies induced by the response had even already been analysed (e.g. D3) and that anti-G protein antibodies have already been used to detect the presence of G protein in cell samples (D2 and D4), it is entirely obvious that antibodies obtained by the vaccination procedure can be used to detect G protein (or placed in a kit for this purpose) and that monoclonal antibodies can be obtained from such a starting point. Hence, at present none of the claims are considered inventive.

It is possible that applicant has indeed invented a much more effective RSV vaccine than is available in the prior art, yet the basis for this increased effectivity must be more clearly reflected in the claims, since it is these that have to be examined for inventive step.

2.3 **Industrial Applicability (Art.33(4) PCT)**

For the assessment of the present claims 15-39, 43, 44 and 47 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

3. **Certain observations (Section VIII)**

3.1 **Clarity (Art.6 PCT)**

The terminology "non-replicating vector" has been replaced by "that will not replicate when introduced into the host to be protected". Such a terminology is fine in method claims (or claims to specific combinations of vectors and hosts) yet unsuitable for product claims where the context in which the product may be used

is irrelevant. The product per se needs to have novel attributes.

If it was stated that the virus could not replicate in the respiratory tract, this would effectively impart a technical feature.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
C12N 15/45, A61K 48/00, G01N 33/53, C07K 16/10

A1

(11) International Publication Number: WO 99/04010

(43) International Publication Date: 28 January 1999 (28.01.99)

(21) International Application Number: PCT/CA98/00697

(22) International Filing Date: 16 July 1998 (16.07.98)

(30) Priority Data:
08/896,442 18 July 1997 (18.07.97) US

(71) Applicant *(for all designated States except US)*: CONNAUGHT LABORATORIES LIMITED [CA/CA]; 1755 Steeles Avenue West, North York, Ontario M2R 3T4 (CA).

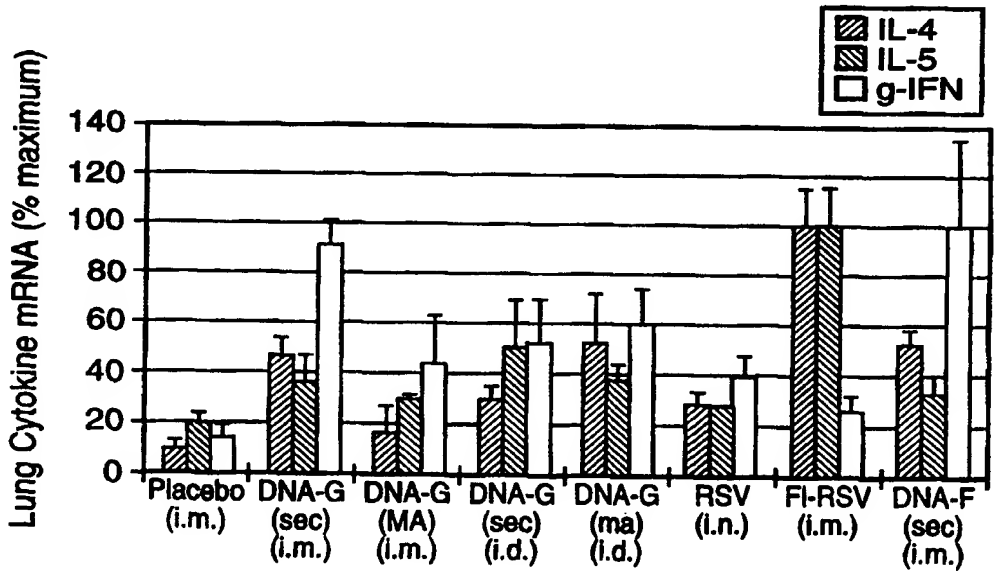
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: LI, Xiaomao [CA/CA]; 106 Glenmanor Way, Thornhill, Ontario L4J 3E5 (CA). SAMBHARA, Suryaprakesh [CA/CA]; 50 Harness Circle, Markham, Ontario L3S 1Y1 (CA). KLEIN, Michel, H. [CA/CA]; 16 Munro Boulevard, Willowdale, Ontario M2P 1B9 (CA).

(74) Agent: STEWART, Michael, I.; Sim & McBurney, 6th floor, 330 University Avenue, Toronto, Ontario M5G 1R7 (CA).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: NUCLEIC ACID VACCINES ENCODING G PROTEIN OF RESPIRATORY SYNCYTIAL VIRUS



(57) Abstract

Non–replicating vectors, such as plasmid vectors, containing a nucleotide sequence coding for a G protein of respiratory syncytial virus (RSV) and a promoter for such sequence, preferably a cytomegalovirus promoter, are described. Such vectors also may contain a further nucleotide sequence located adjacent to the RSV G protein encoding sequence to enhance the immunoprotective ability of the RSV G protein when expressed *in vivo*. Such non–replicating vectors may be used to immunize a host, including a human host, against RSV infection by administration thereto. Such non–replicating vectors also may be used to produce antibodies for detection of RSV infection in a sample.

CLAIMS

What we claim is:

1. An immunogenic composition for *in vivo* administration to a host for the generation in the host of protective antibodies to respiratory syncytial virus (RSV) G protein, comprising a non-replicating vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host, and

a pharmaceutically-acceptable carrier therefor.

2. The composition of claim 1 wherein said first nucleotide sequence encodes a full-length RSV G protein.

3. The composition of claim 2 wherein said nucleotide sequence comprises the nucleotide sequence shown in Figure 2 (SEQ ID NO:1).

4. The composition of claim 2 wherein said first nucleotide sequence comprises the nucleotide sequence encoding a full length RSV G protein having the amino acid sequence shown in Figure 2 (SEQ ID NO:2).

5. The composition of claim 1 wherein said first nucleotide sequence encodes a RSV G protein from which the transmembrane coding sequence and sequences upstream thereto are absent.

6. The composition of claim 5 wherein said non-replicating vector further comprises a heterologous signal peptide encoding nucleotide sequence immediately upstream of the 5'-terminus of said first nucleotide

sequence.

7. The composition of claim 6 wherein said signal peptide encoding sequence encodes the signal peptide for human tissue plasminogen activator.

8. The composition of claim 5 wherein said first nucleotide sequence comprises the nucleotide sequence shown in Figure 3 (SEQ ID NO:3).

9. The composition of claim 5 wherein said first nucleotide sequence comprises a nucleotide sequence encoding a truncated RSV G protein having the amino acid sequence shown in Figure 3 (SEQ ID NO:4).

10. The composition of claim 1 wherein said promoter sequence is a immediate early cytomegalovirus promoter.

11. The composition of claim 1 wherein said second nucleotide sequence is the human cytomegalovirus Intron A.

12. The composition of claim 1 wherein the non-replicating vector is a plasmid vector.

13. The composition of claim 12 wherein the plasmid vector is pXL5 as shown in Figure 4.

14. The composition of claim 12 wherein the plasmid vector is pXL6 as shown in Figure 5.

15. A method of immunizing a host against disease caused by infection with respiratory syncytial virus (RSV), which comprises administering to said host an effective amount of a non-replicating vector comprising:

a first nucleotide sequence encoding an RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from

said vector in the host.

16. The method of claim 15 wherein said first nucleotide sequence encodes a full-length RSV G protein.

17. The method of claim 16 wherein said nucleotide sequence comprises the nucleotide sequence shown in Figure 2 (SEQ ID NO:1).

18. The method of claim 16 wherein said first nucleotide sequence comprises the nucleotide sequence encoding a full length RSV G protein shown in Figure 2 (SEQ ID NO:2).

19. The method of claim 14 wherein said first nucleotide sequence encodes an RSV G protein from which the transmembrane coding sequence and sequences upstream thereto are absent.

20. The method of claim 19 wherein said non-replicating vector further comprises a heterologous signal peptide encoding nucleotide sequences immediately upstream of the 5'-terminus of said first nucleotide sequence.

21. The method of claim 20 wherein said signal peptide encoding sequence encodes the signal peptide for human tissue plasminogen activator.

22. The method of claim 19 wherein said first nucleotide sequence comprises the nucleotide sequence shown in Figure 3 (SEQ ID NO:3).

23. The method of claim 19 wherein said first nucleotide sequence comprises a nucleotide sequence encoding a transverse RSV G protein shown in Figure 3 (SEQ ID NO:4).

24. The method of claim 15 wherein said promoter sequence is an immediate early cytomegalovirus promoter.

25. The method of claim 15 wherein said second nucleotide sequence is the human cytomegalovirus Intron A.

26. The method of claim 1 wherein the non-replicating vector is a plasmid vector.

27. The method of claim 26 wherein said plasmid vector is pXL5 as shown in Figure 4.

28. The method of claim 26 wherein said vector is pXL6 as shown in Figure 5.

29. The method of claim 15 wherein a balanced Th1/Th2 immune response is induced.

30. A method of using a gene encoding a respiratory syncytial virus (RSV) G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein, to produce an immune response in a host, which comprises:

isolating said gene,

operatively linking said gene to at least one control sequence to produce a non-replicating vector, said control sequence directing expression of said RSV G protein when introduced into a host to produce an immune response to said RSV G protein, and

introducing said vector into a host.

31. The method of claim 30 wherein said gene encoding an RSV G protein encodes a full length RSV G protein.

32. The method of claim 30 wherein said gene encoding an RSV G protein encodes an RSV G protein lacking the transmembrane domain and sequences upstream thereto.

33. The method of claim 32 wherein said vectgor further comprises a signal peptide encoding nucleotide sequences immediately upstream of the 5'-terminus of said first nucleotide sequence.

34. The method of claim 33 wherein said signal peptide encoding sequence encodes the signal peptide for human tissue plasminogen activator.

35. The method of claim 30 wherein said at least one control sequence comprises the immediate early cytomegalovirus promoter.

36. The method of claim 35 including the step of:

operatively linking said gene to an

immunoprotection enhancing sequence to produce an enhanced immunoprotection to said RSV G protein in said host.

37. The method of claim 36 wherein said immunoprotection enhancing sequence is introduced into said vector between said control sequence and said gene.

38. The method of claim 37 wherein said immunoprotection enhancing sequence is the human cytomegalovirus Intron A.

39. The method of claim 30 wherein said gene is contained within a plasmid selected from the group consisting of pXL5 and pXL6.

40. A method of producing a vaccine for protection of a host against disease caused by infection with respiratory syncytial virus (RSV), which comprises:

isolating a first nucleotide sequence encoding an RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

operatively linking said first nucleotide sequence to at least one control sequence to produce a non-replicating vector, the control sequence directing expression of said RSV G protein when introduced to a host to produce an immune response to said RSV G protein,

operatively linking said first nucleotide sequence to a second nucleotide sequence to increase expression of said RSV G protein *in vivo* from the vector in the host, and

formulating said vector as a vaccine for *in vivo* administration to a host.

41. The method of claim 40 wherein said vector is selected from group consisting of pXL5 and pXL6.

42. A vaccine produced by the method of claim 40.

43. A method of determining the presence of a respiratory syncytial virus (RSV) G protein in a sample,

comprising the steps of:

(a) immunizing a host with a non-replicating vector to produce antibodies specific for the RSV G protein, said non-replicating vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host,

(b) isolating the RSV G protein specific antibodies;

(c) contacting the sample with the isolated antibodies to produce complexes comprising any RSV G protein present in a sample and said isolated RSV G protein-specific antibodies; and

(d) determining the production of the complexes.

44. The method of claim 43 wherein said vector is selected from the group consisting of pXL5 and pXL6.

45. A diagnostic kit for detecting the presence of a respiratory syncytial virus (RSV) G protein in a sample, comprising:

(a) a non-replicating vector capable of generating antibodies specific for the RSV G protein when administered to a host, the non-replicating vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to

said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host;

(b) isolation means to isolate said RSV G protein-protein-specific antibodies;

(c) contacting means to contact the isolated RSV G specific antibodies with the sample to produce a complex comprising any RSV G protein in the sample and RSV G protein specific antibodies, and

(d) identifying to determine production of the complex.

46. The diagnostic kit of claim 45 wherein said vector is selected from the group consisting of pXL5 and pXL6.

47. A method for producing antibodies specific for a G protein of respiratory syncytial virus (RSV) comprising:

(a) immunizing a host with an effective amount of a non-replicating vector to produce RSV G-specific antibodies, said non-replicating vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host; and

(b) isolating the RSV G-specific antibodies from the host.

48. A method of producing monoclonal antibodies specific for a G protein of respiratory syncytial virus (RSV) comprising the steps of:

(a) constructing a vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host;

(b) administering the vector to at least one mouse to produce at least one immunized mouse;

(c) removing B-lymphocytes from the at least one immunized mouse;

(d) fusing the B-lymphocytes from the at least one immunized mouse with myeloma cells, thereby producing hybridomas;

(e) cloning the hybridomas;

(f) selecting clones which produce anti-RSV G protein antibody;

(g) culturing the anti-RSV G protein antibody-producing clones; and then

(h) isolating anti-RSV G protein antibodies from the cultures.